FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Arthritis Advisory Committee (AAC) Meeting
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
July 13, 2016

AGENDA

The committee will discuss biologics license application (BLA) 761042, for GP2015, a proposed biosimilar to Amgen Inc's Enbrel (etanercept) submitted by Sandoz, Inc. The proposed indications (uses) for this product are (1) Reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active rheumatoid arthritis (RA)((in combination with methotrexate (MTX) or used alone); (2) reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients ages 2 and older; (3) reducing signs and symptoms, inhibiting the progression of structural damage of active arthritis, and improving physical function in patients with psoriatic arthritis (in combination with MTX in patients who do not respond adequately to MTX alone); (4) reducing signs and symptoms in patients with active ankylosing spondylitis; (5) treatment of adult patients (18 years or older) with chronic moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

7:30 a.m.	Call to Order and Introduction of Committee	**Daniel Solomon, MD, MPH** Acting Chairperson, AAC
7:35 a.m.	Conflict of Interest Statement	**Moon Hee Choi, PharmD** Acting Designated Federal Officer, AAC
7:40 a.m.	Overview of the Regulatory Pathway and FDA's Guidance for the Development and Approval of Biosimilar Products in the US	**Leah Christl, PhD** Associate Director, Therapeutic Biologics Therapeutic Biologics and Biosimilars Staff Office of New Drugs (OND), CDER, FDA
8:20 a.m.	Clarifying Questions to the FDA	
8:25 a.m.	FDA Introductory Remarks	**Nikolay P. Nikolov, MD** Clinical Team Leader Division of Pulmonary, Allergy & Rheumatology Products (DPARP) Office of Drug Evaluation II (ODE-II) OND, CDER, FDA
8:30 a.m.	**APPLICANT PRESENTATIONS**	**Sandoz, Inc.**
	Introduction and Concept	**Mark McCamish, MD, PhD** Global Head of Development Sandoz Biopharmaceuticals
	Analytical Demonstration of Similarity	**Martin Schiestl, PhD** Chief Science Officer, Sandoz Biopharmaceuticals
	Non-clinical and Pharmacokinetic Characterization of GP2015	**Oliver von Richter, PhD, FCP** Clinical Pharmacologist, Global Clinical Development Sandoz Biopharmaceuticals

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AGENDA (cont.)

	APPLICANT PRESENTATIONS (cont.)	
	Clinical Confirmation of GP2015 Equivalence to Enbrel®	**Malte Peters, MD** Global Head of Clinical Development Sandoz Biopharmaceuticals
	Use in Clinical Practice	**Jonathan Kay, MD** Timothy S. and Elaine L. Peterson Chair in Rheumatology Professor of Medicine Director of Clinical Research, Rheumatology University of Massachusetts Medical School
	Conclusions	**Mark McCamish, MD, PhD**
10:00 a.m.	Clarifying Questions to Applicant	
10:15 a.m.	**BREAK**	
10:30 a.m.	**FDA PRESENTATIONS**	
	GP2015 Product Quality Review	**Peter L. Adams, PhD** CMC Product Quality Reviewer Division of Biotechnology Review and Research 1 Office of Biotechnology Products Office of Pharmaceutical Quality, CDER, FDA
	GP2015 Statistical Equivalence Testing for Bioactivity	**Meiyu Shen, PhD** CMC Statistical Reviewer Division of Biometrics VI Office of Biostatistics (OB) Office of Translational Sciences (OTS), CDER, FDA
	GP2015 Product Quality Review (cont.)	**Peter L. Adams, PhD**
	Clinical Pharmacology Review	**Yunzhao Ren, MD, PhD** Clinical Pharmacology Reviewer Division of Clinical Pharmacology II Office of Clinical Pharmacology, OTS, CDER, FDA
	Clinical Efficacy Review	**Kathleen Fritsch, PhD** Mathematical Statistician Division of Biometrics III, OB, OTS, CDER, FDA

AGENDA (cont.)

FDA PRESENTATIONS (cont.)

	Clinical Safety and Immunogenicity Review, Considerations for Extrapolation and Summary of FDA Presentation	**Rachel Glaser, MD** Medical Officer DPARP, ODE-II, OND, CDER, FDA
12:00 p.m.	Clarifying Questions to FDA	
12:15 a.m.	**LUNCH**	
1:15 p.m.	**OPEN PUBLIC HEARING**	
2:45 p.m.	Charge to the Committee	**Nikolay P. Nikolov, MD**
3:00 p.m.	Questions to the Committee and Committee Discussion	
3:30 p.m.	**BREAK**	
3:45 p.m.	Questions to the Committee and Committee Discussion	
5:00 p.m.	**ADJOURNMENT**	